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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/419,461	10/15/1999	OMAR S. KHALIL	6351.US.P2	1303

23492 7590 09/10/2002

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EXAMINER

KREMER, MATTHEW J

ART UNIT

PAPER NUMBER

3736

DATE MAILED: 09/10/2002

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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT PAPER

15

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Commissioner of Patents and Trademarks

Attached to the Examiner's Answer is a copy of the Information Disclosure Statements filed on 6/10/2002 and 8/15/2002. Both IDS's have been considered.

Matthew Kremer
Assistant Examiner
Art Unit 3736



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GROUP 3700

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Paper No. 15

Application Number: 09/419,461

Filing Date: October 15, 1999

Appellant(s): KHALIL ET AL.

David L Weinstein
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed June 24, 2002.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

The rejection of claims 1-6, 8-13, 15-24, 26-31, 33-42, and 44-52 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) *ClaimsAppealed*

The copy of the appealed claims 1-6, 8-13, 15-24, 27-31, 33-42, and 44-51 contained in the Appendix to the brief is correct. Claim 26 has been amended in response to the after final amendment, paper number 12, filed on 6/24/2002. The temperature range in claim 26 was changed from "about 15°C to about 42°C" to "about 10°C to about 42°C" to make it consistent with page 17, lines 5-6 of the specifications.

(9) *Prior Art of Record*

5,978,691	Mills	11-1999
5,782,755	Chance et al.	7-1998
5,873,821	Chance et al.	02-1999

Laufer, Jan, Rebecca Simpson, Matthias Kohl, Matthias Essenpreis, and Mark Cope. "Effect of Temperature on the Optical Properties of *Ex Vivo* Human Dermis and Subdermis" *Phys. Med. Biol.*, vol 43 (1998), pp. 2479-2489

Khalil et al. U.S. copending Application No. 09080470

(10) *Grounds of Rejection*

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-3, 6, 8-13, 15-21, 24, 26-31, 33-39, 42, and 44-51 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,978,691 to Mills in view of the journal publication "Effect of temperature on the optical properties of ex vivo human dermis and subdermis" by Laufer et al. This rejection is set forth in prior Office Action, Paper No. 7.

Claims 4-5, 22-23, and 40-41 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,978,691 to Mills in view of the journal publication "Effect of temperature on the optical properties of ex vivo human dermis and subdermis" by Laufer et al. in view of U.S. Patent 5,782,755 to Chance et al. This rejection is set forth in prior Office Action, Paper No. 7.

Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,978,691 to Mills in view of the journal publication "Effect of temperature on the optical properties of ex vivo human dermis and subdermis" by Laufer et al. in view of U.S. Patent 5,873,821 to Chance et al. This rejection is set forth in prior Office Action, Paper No. 7.

Claims 1-3, 8-13, 15-16, 19-21, 26-31, 33-34, 37-39, 44-46, and 49 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13, 15, 33, and 35-36 of U.S. copending Application No. 09080470 to Khalil et al. in view of the journal publication "Effect of temperature on the optical properties of *ex vivo* human dermis and subdermis" by Laufer et al. This rejection is set forth in prior Office Action, Paper No. 7.

(11) Response to Argument

Appellant alleges that the Examiner has failed to make a *prima facie* showing of obviousness for the following reasons: 1) the method described in Laufer et al. is used only with excised tissue; 2) Mills performs optical measurement before the samples were allowed to equilibrate at the temperature at which optical data are collected; and 3) Mills discloses nothing relating to the effect of temperature change upon an average sampling depth that is confined within a temperature controlled region in the body part.

In regard to the first and third reasons, the information from Laufer et al. discloses that the method of Mills causes the average sampling depth in a tissue to change when the temperature is changed. In other words, the change in the average sampling depth due to temperature change is a naturally occurring phenomenon. This naturally occurring phenomenon is inherent as a tissue property whether Mills discloses the phenomenon or not. The argument that the information is only applicable to excised

tissue is not persuasive since Laufer et al. teaches that the optical properties of skin is particularly relevant during noninvasive examination of brain and muscle tissue as well as glucose. (lines 4-6 of the Introduction of Laufer et al.). Laufer et al. is suggesting that the motivation for their experiments is to aid in the analysis of noninvasive procedures. This motivation would give an indication that the principles disclosed would be applicable in excised or intact tissue.

In regard to the second reason, the Applicant relies on the information disclosed in claim 19, column 17, lines 63-64, and claim 34 to argue that Mills teaches away from equilibration of the biological sample at a given temperature. Although these passages refer to inducing a temperature change while emitting and detecting the radiation, column 9, lines 1-22 of Mills teaches another embodiment of the method that allows temperature equilibration as previously stated in the Office Action mailed on 11/6/2001. Mills teaches that to generate a single data point, the temperature induction means is used to bring the finger to a known temperature and the temperature measurement means will be used to confirm the temperature and adjust the temperature induction means if necessary. (column 9, lines 1-5 of Mills). In this procedure, there is a clear indication that there is a desired temperature to be achieved for measurement before the light emitter is used. The confirmation and correction procedure is used to establish the temperature of the finger. The inference that can be made is that a stable temperature within the finger is required at the time of measurement; otherwise, the need to establish and correct for a given temperature would be unnecessary. Further,

multiple measurements using different wavelengths or multiple measurements using the same wavelength are taken at a given temperature which further implies that the tissue must be at equilibration at the given temperature.

In response to the Applicant's argument that the combination is a piecemeal construction, the Examiner disagrees. The Examiner is not excluding the concept that the Laufer et al. reference is used on excised tissue but is applying the teachings from those experiments to indicate that there is a naturally occurring phenomenon of the change in the average sampling depth due to the change in temperature that is inherent in the method of Mills. The combination does not exclude the non-equilibration of the sample in Mills but uses another embodiment of the method of Mills that includes equilibration.

Since the rejections of claims 1-3, 6, 8-13, 15-21, 24, 26-31, 33-39, 42, and 44-51 are deemed proper due to the reasons stated above and the applicant provides no other arguments than the supposed deficiencies of intact tissue, the equilibration of the tissue at a given temperature for each measurement, and the average sampling depth changes as the temperature of the tissue changes, and the failure of the secondary references to teach the deficiency, the rejections of the subsequent dependent claims are also deemed proper.

Examiner acknowledges Applicant's notice of filing a Terminal Disclaimer to overcome the rejection under the judicially created doctrine of obviousness-type double patenting when claims 13, 15, 33, and 35-36 of U.S. Patent Application of 09/080,470 are issued.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,



MJK
September 6, 2002

Conferees 




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